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A Comprehensive Risk Assessment of Mortality Following Donation after Cardiac Death Liver Transplant – An Analysis of the National Registry

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Abstract

Background and Aims—Organ scarcity has resulted in increased utilization of *donation after cardiac death* (DCD) donors. Prior analysis of patient survival following DCD liver transplantation has been restricted to single institution cohorts and a limited national experience. We compared the current national experience with DCD and DBD livers to better understand survival after transplantation.

Methods—We compared 1,113 DCD and 42,254 DBD recipients from the Scientific Registry of Transplant Recipients database between 1996 and 2007. Patient survival was analyzed using Kaplan-Meier methodology and Cox regression.

Results—DCD recipients experienced worse patient survival compared to DBD recipients ($p < 0.001$). One and three year survival was 82% and 71% for DCD compared to 86% and 77% for DBD recipients. Moreover, DCD recipients required re-transplantation more frequently (DCD 14.7% *versus* DBD 6.8%, $p < 0.001$), and re-transplantation survival was markedly inferior to survival after primary transplant irrespective of graft type. Amplification of mortality risk was observed when DCD was combined with cold ischemia time > 12 hours (HR=1.81), shared organs (HR=1.69), recipient hepatocellular carcinoma (HR=1.80), recipient age > 60 years (HR=1.92), and recipient renal insufficiency (HR=1.82).

Conclusions—DCD recipients experience significantly worse patient survival after transplantation. This increased risk of mortality is comparable in magnitude to, but often

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exacerbated by other well-established risk predictors. Utilization decisions should carefully consider DCD graft risks in combination with these other factors.

INTRODUCTION

Dramatic improvements in patient survival since the introduction of liver transplantation have led to transplantation of “sicker” patients and increasing utilization of expanded criteria grafts.^{1, 2} These trends are a clear indication of the increasing discrepancy between organ supply and demand.^{1, 3} One example of increasing use of high risk grafts is the dramatic increase in *donation after cardiac death* (DCD) liver transplants in the United States (US), rising over the past decade from <1% to 6.4% of all deceased donor liver transplants.¹

However, DCD liver transplantation has been associated with inferior outcomes including higher rates of graft failure and biliary complications compared with *donation after brain death* (DBD) transplants.^{4–7} While it has been established that DCD recipients experience worse graft survival,^{4, 7–13} previous reports^{4, 5, 8} have generally failed to identify a significant difference in patient survival between DCD and DBD recipients save for a select few single institution reports¹². However, these analyses were restricted to small cohorts from single institution reports and a limited national experience.

Recently, the Centers for Medicare and Medicaid Services (CMS) published conditions of participation enforcing mandatory reporting of transplant center performance. In addition to quality improvement, the policy fosters transparency in communicating risk to better inform decision making by patients, clinicians, payers, and policy makers. As such, an enhanced understanding of the risks and outcomes associated with DCD grafts is of great importance. This paper, using current national data, compares patient survival after DCD and DBD liver transplantation and examines differences in survival in the context of other well-established donor and recipient risk predictors.

METHODS

Data source and study population

We performed a retrospective analysis using data from the Scientific Registry of Transplant Recipients (SRTR) database. The SRTR contains information submitted by members of the Organ Procurement and Transplantation Network (OPTN) on all wait-listed and transplanted patients and is supplemented by the Social Security Death Master File. The study population includes all deceased donor liver transplant recipients performed in the US from April 1, 1996 to October 1, 2007 representing 1,113 DCD and 42,254 DBD recipients. Pediatric (age <18 years), multi-organ transplants (except simultaneous liver-kidney transplants), and recipients with a previous liver transplant were excluded. There were no partial DCD transplants in this cohort; as such, only whole DBD liver transplants were included in the analysis. Recipients without follow-up (n=336, 0.6%) were also excluded.

Data analysis

The primary outcome measure was patient mortality. Patient survival was calculated from date of transplant to death or last known follow-up. Potentially confounding donor and recipient factors were examined. Donor factors included age, race, gender, body mass index (BMI), cause of death, utilization of vasopressors, terminal serum creatinine, warm (WIT) and cold ischemia time (CIT), and rates of regional and national sharing. Recipient factors at time of transplant included age, race, gender, BMI, liver disease etiology, calculated Model for End-stage Liver Disease (MELD) score, hepatitis C virus (HCV), hepatocellular carcinoma (HCC), mechanical, ventilated or organ perfusion support, medical condition (at

home, in hospital, in intensive care unit [ICU]), prior abdominal surgery, renal insufficiency (defined as terminal serum creatinine >1.5, hemodialysis, or simultaneous liver-kidney transplant), international normalized ratio, total bilirubin, and albumin were examined. Recipients were also dichotomized according to year of transplant (1996–2001 versus 2002–2007) for comparison of survival outcomes.

Student's t-tests and chi-square tests were used for comparison of continuous and categorical variables respectively. Patient survival analysis was performed using Kaplan-Meier methods and compared according to the log-rank test. Cox proportional hazards regression was used to analyze adjusted patient survival and evaluate risk predictors. DCD and DBD survival was compared after adjusting for all donor and recipient differences identified in Table 1. Stratified analyses were performed to examine binary interactions between DCD graft type and other identified important covariates. Hazard ratios (HR) with 95% confidence intervals (CI) are reported. Additionally, the synergy index was calculated to examine evidence of interaction.^{14, 15} A synergy index of one is equivalent to no interaction. A p-value < 0.05 was considered statistically significant. Data was analyzed using StataSE10 (Stata Corp, College Station, TX). This study was deemed exempt by the Northwestern University Institutional Review Board.

RESULTS

Study population

Recipients of DCD and DBD transplants differed in several important aspects (Table 1). While DCD recipients were older (DCD 53.5 ± 9.5 years versus DBD 51.6 ± 10.1 years, $p < 0.001$), they generally displayed lower risk characteristics compared with DBD recipients. They had lower MELD scores (DCD 18.8 ± 8.2 versus DBD 20.2 ± 9.1 , $p < 0.001$), were less likely to be on life support (DCD 5% versus DBD 7%, $p = 0.004$), and were less likely to be admitted to a hospital ward (DCD 13% versus DBD 16%) or ICU (DCD 10% versus DBD 15%) at transplant ($p < 0.001$). There was however a greater proportion of HCC recipients in the DCD cohort (DCD 20% versus DBD 13%, $p < 0.001$). Additionally, DCD transplantation was associated with more favorable factors of graft quality such as donor age (DCD 36.4 ± 15.4 years versus DBD 40.2 ± 17.6 , $p < 0.001$), CIT (DCD 7.7 ± 3.6 hours versus DBD 8.0 ± 3.7 , $p = 0.12$), and lower rates of vasopressor utilization (DCD 27% versus DBD 83%, $p < 0.001$). The average WIT for DCD transplants was 15.6 ± 9.4 minutes. DCD transplants were associated with higher rates of regional and national sharing (DCD 33% versus DBD 27%, $p < 0.001$).

Patient Survival

DCD recipients experienced worse patient survival following transplantation compared to DBD recipients ($p < 0.001$) (Figure 1). One and three year patient survival rates were 82% and 71% for DCD recipients compared to 86% and 77% for DBD recipients. Interestingly, there was no improvement in survival with growing experience (Figure 2). DCD recipients in the early cohort (1996–2001) experienced similar patient survival to those in the more recent cohort (2002–2007) ($p = 0.49$). Additionally, re-transplantation was performed more than twice as often among DCD recipients (DCD 14.7% versus DBD 6.8%, $p < 0.001$). When patient survival after re-transplantation was examined according to the graft type of the original transplant (DCD versus DBD), there were no differences in subsequent patient survival ($p = 0.88$) (Figure 3). However, it is clear that re-transplant survival for both groups was markedly inferior to survival after primary transplant. Patient survival was 71% and 59% at one and three years after re-transplant for recipients who originally underwent DCD transplantation and 68% and 60% after DBD transplantation.

Mortality Risk Predictors

DCD grafts were associated with an increased hazard of mortality (HR=1.29, 95% CI=1.15–1.45). However, this increased mortality risk for DCD recipients is comparable in magnitude to other well-known risk predictors of patient mortality such as donor age > 40 years (HR=1.40, 95% CI=1.35–1.45), CIT > 12 hours (HR=1.20, 95% CI=1.15–1.25), and regional/national sharing (HR=1.15, 95% CI=1.11–1.20). Notable recipient risk predictors including age > 60 years (HR=1.40, 95% CI=1.34–1.46), HCV (HR=1.39, 95% CI=1.34–1.45), HCC (HR=1.33, 95% CI=1.27–1.39), and renal insufficiency at transplant (HR=1.35, 95% CI=1.28–1.42) are also similar in scale to the mortality risk of DCD (Figure 4). Moreover after adjusting for differences in donor and recipient factors between DCD and DBD recipients (see Table 1), DCD recipients (adjusted HR = 1.44, 95% CI = 1.24–1.67) had a markedly increased mortality risk compared to DBD recipients.

Stratified analysis was conducted to examine binary interactions between these risk predictors and DCD graft type (Table 2). Both donor age and HCV status exacerbate risks associated with DCD grafts. However, the Rothman synergy index (S) suggests that the risks associated with each factor separately was less than the sum of the two. However, there was a synergistic effect upon patient mortality between DCD and either CIT > 12 hours or sharing. Additionally, there was an escalation in the hazard of mortality associated with HCC status, recipients > 60 years old, and those with renal insufficiency at time of transplant when combined with DCD grafts.

DISCUSSION

In the current era of increasing transparency and accountability, an improved understanding of post-transplantation outcomes takes on even greater significance. Herein, we demonstrate that DCD recipients experience significantly worse patient survival after transplantation compared with DBD recipients. This increased mortality risk remains significant after adjusting for donor and recipient factors including those that might represent a selection bias such as rates of HCC and HCV. However, it should be noted that many of these patients may have not been offered a DBD liver, so survival results of 82% at one year and 71% at three years should be considered in light of the high mortality risks associated with remaining on the waiting list. This is especially salient given that 30-day mortality is between 19–47% for patients with a MELD greater than 20.

Moreover, this increased hazard for mortality is similar in magnitude to the mortality risks of other well-known donor and recipient factors accepted by the transplant community. These risk factors include the utilization of grafts from older donors, and transplanting recipients with advanced age, HCV, or HCC. Utilization of poorer quality organs is occurring in response to the increasing divergence between organ supply and demand. An improved understanding of the combined risks associated with different donor and recipient factors is vital to utilization decisions. Transplant policy should incorporate adequate risk adjustment into the measurement of transplant center performance and into improving informed consent in order to maximize the individual and societal benefits associated with transplantation.

Due to the more than ten-fold rise in annual DCD liver transplants over the past decade, it is important to reconsider the impact of DCD utilization on patient survival. While it has been established that DCD recipients experience worse graft survival,^{4, 7–13} previous reports have generally failed to identify a significant difference in patient survival between DCD and DBD recipients save for small single center experiences.¹² These studies are marred by limited sample sizes inherent to single institution studies and an early national experience. In order to detect a 5% difference in patient survival, more than 500 DCD transplants are

needed for analysis for a power of 0.8 and p-value of 0.05. Currently, with more than 1,000 DCD transplants performed in the US, sufficient sample sizes are available for analysis and are capable of identifying discrete differences in survival. We have demonstrated that mortality risks are nearly 30% higher amongst DCD recipients and even greater after risk adjustment. Moreover, there is no evidence of any experiential improvement in survival after DCD transplantation over the past decade suggesting other dominant pathophysiologic mechanisms that merit further investigation.

DCD transplantation has been promoted either as a definitive therapy or failing this as a “bridge” for patients on the waiting list who are unlikely to receive a timely DBD transplant. However, given higher re-transplantation rates and clearly worse survival rates after re-transplantation compared with primary transplantation, this strategy should be employed cautiously.

Increased risks associated with transplantation for older recipients, recipients with HCC or HCV, or using older donors have been widely accepted to extend transplantation to greater numbers of patients in need. In this paper, we demonstrate that the increased mortality risk associated with transplantation of DCD livers is very comparable to the risks associated with these other well-accepted risk predictors. Furthermore by considering the interactions between these risks, a more precise understanding of the impact of receiving a DCD graft can be achieved. Increases in mortality were much lower amongst younger recipients (<60 years old), recipients without HCV, recipients without HCC, and recipients without renal insufficiency at time of transplant. Additionally, those who received DCD grafts from donors <40 years old or with a CIT <12 hours also experienced greatly improved outcomes.

Decreased survival for HCC recipients of both DCD and DBD livers may be surprising given the well-documented fact that HCC patients generally have a lower calculated MELD score and corresponding liver disease severity at time of transplant. We further examined this and determined that HCC patients received significantly older livers (41.4 versus 39.4 years, $p<0.001$), more DCD livers (10.4% versus 7.8%, $p=0.001$), were older at transplant (55.8 versus 50.8 years, $p<0.001$), and had higher rates of HCV (11.4% versus 5.5%, $p<0.001$).

Improving our understanding of these risks is important to inform decision-making by patients, clinicians, and policy-makers. Current risk assessment tools have fallen short. Donor risk index, a popular measure of graft quality according to seven identified donor factors, has been demonstrated to have poor predictive value with a c-statistic of 0.53.¹⁶ MELD score which has been established as an effective predictor of 90 day wait-list mortality (c-statistic=0.83)¹⁷ has little predictive value for post-transplantation survival (c-statistic=0.54).¹⁸ Given the mandatory reporting of transplant center outcomes and the CMS eligibility contingent on adequate performance, it is important to ensure adequate risk adjustment and to develop better risk-assessment tools to prevent risk aversion and protect access to vulnerable populations. Improving our ability to identify and quantify risks by understanding important factors and the interplay between them will enable better utilization decisions and physician-patient communication.

Strengths and Limitations

This study has two key strengths. It is based on analysis of national census data of DCD transplantation and focuses on an objective outcome measure such as mortality.

This analysis is subject to some important limitations. Given the retrospective nature of the analysis, differences in patient selection for DCD versus DBD transplantation may be present. Many different recipient factors were considered, and we generally identified less

risky characteristics among DCD recipients (lower MELD scores, lower proportions of recipients on life support or with renal insufficiency prior to transplant, and more recipients at home prior to transplant rather than admitted to hospital or ICU). However, there were a greater proportion of HCC recipients in the DCD cohort. This is problematic given the difficulty in identifying all recipients with HCC in the SRTR dataset, especially those who failed to receive MELD exception points. Moreover, there may be differences in the severity of HCC between DCD and DBD recipients. Specifically, DCD grafts represent a potentially attractive option for timely transplantation of HCC recipients in the absence of a living donor when a patient does not meet criteria for MELD exception points. Unfortunately, sufficient data regarding the severity of HCC is unavailable to answer this question. However, we still identified a 25% increased mortality risk associated with DCD transplantation in recipients without HCC. Furthermore, in the multivariate analysis after adjustment for HCC status, DCD remained significantly associated with increased mortality risk.

Finally, decision-making regarding utilization of these grafts are guided by DCD and DBD post-transplantation survival, but are inadequate without consideration of the mortality risks associated with remaining on the waiting list. Determining which patients will benefit from receiving a DCD graft and thereby, being removed earlier from the waitlist, is a question that has not been answered in this study, and would be more appropriately addressed by employing decision analysis methods.

CONCLUSIONS

DCD recipients experienced worse survival after transplantation compared with DBD recipients, particularly after risk-adjustment. However, this increased mortality is comparable in magnitude to the mortality risk with other well-established and accepted risk predictors such as advanced recipient age, recipients with HCV or HCC, and older donors. Additionally, combining DCD grafts with these risk factors results in an increase in the mortality risk and should be carefully considered in utilization decisions. An improved understanding of risk and risk factor interactions is important for informing decision-making by patients, clinicians, and policy-makers.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ABBREVIATIONS

DCD	Donation after Cardiac Death
US	United States
DBD	Donation after Brain Death
CMS	Centers for Medicare and Medicaid Services
SRTR	Scientific Registry of Transplant Recipients
OPTN	Organ Procurement and Transplantation Network
BMI	Body Mass Index
WIT	Warm Ischemia Time
CIT	Cold Ischemia Time
MELD	Model for End-stage Liver Disease

HCV	Hepatitis C Virus
HCC	Hepatocellular Carcinoma
ICU	Intensive Care Unit
RI	Renal Insufficiency
HR	Hazard Ratios
CI	Confidence Intervals

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Figure 1.

Figure 2.

Figure 3.

Donor Factors:	HR	95% CI
DCD graft (ref: DBD)	1.29	1.15-1.45
Age > 40 years	1.40	1.35-1.45
Cold ischemia time > 12 hours	1.20	1.15-1.25
Sharing (ref: local donor)	1.15	1.11-1.20

Recipient Factors:

Age > 60 years	1.40	1.34-1.46
HCV+	1.39	1.34-1.45
HCC+	1.33	1.27-1.39
Renal insufficiency	1.35	1.28-1.42

* HR=hazard ratio, CI=confidence interval, DCD=donation after cardiac death, DBD=donation after brain death, HCV=hepatitis C virus, HCC=hepatocellular carcinoma.

Figure 4.

Table 1

Donor and recipient characteristics for DCD and DBD liver transplant recipients.

	DCD (n=1,113)	DBD (n=42,254)	
Recipient characteristics	mean $\pm$ SD	mean $\pm$ SD	p-value
Age at transplant (years)	53.5 $\pm$ 9.5	51.6 $\pm$ 10.1	<0.001
Calculated MELD score	18.7 $\pm$ 8.2	20.2 $\pm$ 9.1	<0.001
Body mass index	28.0 $\pm$ 5.8	27.9 $\pm$ 5.9	0.83
	n (%)	n (%)	
Gender (male)	781 (70.2%)	27,853 (65.9%)	0.003
Race/ethnicity			0.001
white	873 (78.4%)	31,710 (75.1%)	
black	93 (8.4%)	3,484 (8.3%)	
hispanic	121 (10.9%)	4,948 (11.7%)	
other	25 (2.3%)	2,055 (4.9%)	
Liver disease etiology			0.03
acute hepatic necrosis/fulminant	94 (8.5%)	3,925 (9.3%)	
non-cholestatic cirrhosis	787 (70.7%)	29,419 (60.6%)	
cholestatic cirrhosis	101 (9.1%)	4,274 (10.1%)	
metabolic disease	26 (2.3%)	1,120 (2.7%)	
malignant neoplasms	98 (8.8%)	2,888 (6.8%)	
missing	1 (0.1%)	69 (0.2%)	
Hepatitis C virus serology			<0.001
positive	417 (47.0%)	16,150 (45.9%)	
unknown	155 (14.9%)	4,056 (10.3%)	
Hepatocellular carcinoma	247 (20.2%)	6,887 (13.0%)	<0.001
Mechanical, ventilated or organ perfusion support at transplant	55 (4.9%)	3,021 (7.2%)	0.004
Renal insufficiency at transplant	289 (26.7%)	9,378 (29.1%)	0.08
Medical condition			<0.001
at home	862 (77.5%)	29,063 (68.8%)	
in hospital (not ICU)	144 (12.9%)	6,678 (15.8%)	
in ICU	107 (9.6%)	6,492 (15.4%)	
Donor characteristics	mean $\pm$ SD	mean $\pm$ SD	
Age (years)	36.4 $\pm$ 15.4	40.2 $\pm$ 17.6	<0.001
Body mass index	25.9 $\pm$ 5.5	25.9 $\pm$ 5.7	0.98
Cold ischemia time (hours)	7.7 $\pm$ 3.6	8.0 $\pm$ 3.7	0.12
Warm ischemia time (minutes)	15.6 $\pm$ 9.4		
	n (%)	n (%)	
Gender (male)	724 (65.1%)	25,006 (59.2%)	<0.001
Race/ethnicity			<0.001

	DCD (n=1,113)	DBD (n=42,254)	
Recipient characteristics	mean $\pm$ SD	mean $\pm$ SD	p-value
white	952 (85.5%)	30,642 (72.5%)	
black	88 (7.9%)	5,641 (13.4%)	
hispanic	54 (4.9%)	4,737 (11.2%)	
other	15 (1.4%)	1,134 (2.7%)	
Cause of death			<0.001
anoxia	321 (28.8%)	4,385 (10.4%)	
stroke	241 (21.7%)	18,874 (44.7%)	
trauma	479 (43.0%)	17,871 (42.3%)	
other	61 (5.5%)	732 (1.7%)	
Pressors prior to donation	297 (26.7%)	34,852 (82.5%)	<0.001
Regional/national sharing	363 (32.6%)	11,443 (27.1%)	<0.001

Table 2

Stratified analysis of patient survival examining interactions between graft type (DCD versus DBD) and other donor and recipient risk predictors.

Risk predictor	HR	95% CI	Synergy index	95% CI
Donor age				
DBD, donor < 40 years (reference)	1.00	NA		
DBD, donor > 40 years	1.40	1.35–1.45		
DCD, donor < 40 years	1.46	1.24–1.71		
DCD, donor > 40 years	1.64	1.39–1.94	0.74	0.59–0.93
Cold ischemia time (CIT)				
DBD, CIT < 12 hours (reference)	1.00	NA		
DBD, CIT > 12 hours	1.19	1.14–1.23		
DCD, CIT < 12 hours	1.24	1.09–1.42		
DCD, CIT > 12 hours	1.81	1.44–2.29	1.88	1.40–2.53
Sharing				
DBD, local donor (reference)	1.00	NA		
DBD, regional/national sharing	1.14	1.10–1.19		
DCD, local donor	1.20	1.04–1.39		
DCD, regional/national sharing	1.69	1.39–2.04	2.03	1.59–2.59
Hepatitis C virus (HCV) status				
DBD, HCV – (reference)	1.00	NA		
DBD, HCV +	1.39	1.34–1.45		
DCD, HCV –	1.48	1.23–1.77		
DCD, HCV +	1.63	1.35–1.96	0.72	0.56–0.94
Hepatocellular carcinoma (HCC)				
DBD, HCC – (reference)	1.00	NA		
DBD, HCC +	1.32	1.25–1.39		
DCD, HCC –	1.25	1.09–1.42		
DCD, HCC +	1.80	1.43–2.28	1.40	1.01–2.01
Recipient Age				
DBD, recipient < 60 years (reference)	1.00	NA		
DBD, recipient > 60 years	1.40	1.34–1.46		
DCD, recipient < 60 years	1.24	1.08–1.42		
DCD, recipient > 60 years	1.92	1.55–2.38	1.44	1.09–1.90
Renal insufficiency (RI)				
DBD, no RI	1.00	NA		
DBD, RI +	1.35	1.28–1.42		
DCD, no RI	1.24	1.06–1.44		
DCD, RI +	1.82	1.44–2.29	1.39	1.06–1.82